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August 19, 2024

Re: Clinical Medical Societies Response to the Request for Information on the National Institutes of Health Draft Public Access Policy (89 FR 51537)

Dr. Tabak,

Thank you for the opportunity to respond to the National Institute of Health (NIH) Draft Policy on Public Access of Federally Funded Research. The entirety of these comments represents 12 non-profit, US based, medical Societies that publish some of the top clinical journals.

We will address several issues posed by the draft policy including:

- Rights of researchers to determine reuse of content
- Value added by publishers to the accepted manuscript version of papers
- Research integrity and trust in the American scientific enterprise
- Applicable article types
- Implementation date

The Earlier Implementation Date is Problematic

At the time of the Draft Plan, many organizations requested more time to facilitate communication, education, and technical changes required to implement this draft policy. We encourage the NIH to produce an education campaign to ensure grantees understand the changes. Authors will need to determine if journals will continue to bulk deposit and if not, what steps they need to take to ensure the article is deposited.

Also, grantees receiving funding now will publish results of this work after the implementation date and have not reviewed and understood the new criteria. How to accommodate compliance with any papers that may be published after the closure of the grant period will also need to be considered.

The majority of manuscripts deposited into PubMed Central are done either via bulk deposit by journal publishers or one-by-one by journal publishers on behalf of authors. As the current Publisher Participation Agreements between the National Library of Medicine

(NLM) and publishers will be invalidated as of October 1, 2025, new agreements will need to be negotiated.

We remain concerned that there will not be enough time to roll out an implementation plan by October 1, 2025.

Certain Article Types Should Not Be Included

We are disappointed that the draft policy failed to clarify which specific article types would be subject to the policies and which would not. Our journals frequently invite experts to write commentaries, perspectives, state-of-the-art reviews, and educational content to help clinicians put the research into the context of their daily practice and to help patients understand the implications of the results. These opinions may also highlight limitations of the study or areas that require further exploration.

As funded researchers are incentivized to connect as many manuscripts to their grant activities as possible, it is not uncommon for an author to claim funding support on manuscripts of opinion. However, no one would assert that an editorial is the work product of a grant. As such, we are once again asking that the policy be restricted to specific articles detailing the results of original research funded by the grant and not inclusive of any work a grantee publishes over the course of the grant period.

Draft Guidance on Government Use License and Rights

Publishers have facilitated the goals of the NIH, under congressional requirements, to make publicly available on PubMed Central the results of research as accepted by journals within 12 months of publication. This new draft policy goes too far in assuming rights that Congress has not authorized, that the Office of Management and Budget (OMB) has specifically not claimed and is contrary to copyright law. Further, federal purpose is a non-statutory claim.

As the NIH is aware, journals not only facilitate the timely peer review by our expert editors, most of whom are physicians, of submitted manuscripts leading to improvements to the manuscripts, but journals staff and/or editors also routinely conduct an intensive integrity review (including appropriate trial registration, required IRB approvals, adherence to CONSORT and other reporting standards, plagiarism checks, authorship criteria, disclosure of financial relationships and other potential conflicts of interest, checking that figures are free of inappropriate manipulation, adherence to data sharing requirements,

etc.) These research integrity tools require staff, vendors, platforms, and extensive trainings for staff and editors.

Further, our expert editors ensure that abstracts, titles, and conclusions accurately represent the results of the research. The editors also facilitate methodological and biostatistical reviews of content in addition to the clinical content review. It is not uncommon for submitted manuscripts to go through more than one review cycle. In fact, it is extremely rare that revisions are not requested, triggering further review of those changes.

Non-profit medical societies have a vested interest in helping the authors improve their manuscripts to be the best output possible. This work benefits us, benefits the authors, benefits the clinicians and patients they treat, and ultimately benefits the NIH. The proposed policy would require societies to provide this version with its vastly added value to the public with no opportunity for embargo and loss of control over rights for reuse or creation of derivatives. This draft policy severely undervalues the work that journals and societies like ours put into the improvement of submitted manuscripts.

While we appreciate that the draft policy does not limit publisher's ability to license content by requiring a CC BY license, the NIH has essentially taken those rights without any requirement for attribution.

This policy draft would give the NIH the right to reproduce papers, create derivative works, and allow others to do the same on the version of the manuscripts that journals have invested resources in to improve.

It is extremely concerning that the NIH is requiring researchers, some of whom may have minimal federal funding associated with a manuscript, to hand over rights to the NIH that may allow others (not defined or limited) to reproduce AND create derivative works of the accepted manuscript. In essence, this draft policy could allow a third party or the government to recreate our journals in a different format or create new products with the content with no attribution to the author or the publisher. This is a direct violation of copyrights held by the authors and the publishers who accepted the work and possess a significant risk of perpetuating misinformation.

More concerning is that the NIH is reserving the rights to alter the content. While we expect it is not the intent of the NIH to modify published research papers, as written, the draft policy allows for this possibility. As presented in the draft policy, the NIH would have the right to alter the results described in a manuscript to fit a political agenda or add inappropriate content to a paper—without the consent, and yet under the byline, of an author.

Our journals are seen as trusted sources of clinical content directly affecting patient care. As scientific and clinical practice societies, we take that role seriously through our manuscript reviews, our conflict-of-interest policies, and our processes for handling issues of research integrity. Our journals and our non-profit organizations serve a mission to attract and disseminate the highest quality and most impactful clinical content to the communities we serve and the public.

As stewards of the research published in our journals, we manage permission requests on behalf of our authors, and it is not uncommon to receive requests that are inappropriate. Safeguarding science from industry spin or ideological cherry picking of data points is another way that we expend resources on ensuring the integrity of the content.

This draft policy requiring authors to deputize the NIH to extend to others the right to use or alter content without permission and without attribution removes those safeguards and puts the reputations of our journals, our societies, and our researcher members at significant risk.

Further, this draft policy would allow the NIH to grant permission to third parties to ingest our copyrighted content into online indices and AI tools. AI companies are already taking our full text content out of PubMed Central and using it to train their AI tools without our permission, without attribution, and without any renumeration. This is an area where societies could use support from our government instead of allowing the government to enable this unauthorized use of our content.

At a time when public trust in science is fragile and trust in government institutions is at historically low levels, a policy that allows the government to manipulate scientific research papers carries unintended consequences that may erode trust even further. Researchers, patients, and policymakers trust that the content in PubMed and PubMed Central come from sources that carefully review and publish content that is accurate and impactful.

Using non-statutory “federal purpose” language and declaring a “Government license” is unprecedented and unnecessary for the purpose of providing the public with access to the accepted manuscripts.

As has been noted in the 2025 reports from both the House Subcommittee on Commerce, Justice, Science Appropriations and the Senate Appropriations Committee Commerce-Justice-Science that accompanied their budgets, “Researchers should have the right to choose how and where they publish or communicate their research and should not be forced to disseminate their research in ways or under licenses that could harm its integrity or lead to its modification without their express consent.”

In fact, when our members are given a choice between a Creative Commons Attribution Only license (CC BY) or a more restrictive version that does not allow for derivatives or use in commercial activities (CC BY NC-ND), authors overwhelmingly select the more restrictive licenses.

The NIH draft policy takes an extremely bold step in requiring rights to a version of the manuscript that has been improved, vetted, and given a branded stamp of approval by our non-profit scientific organizations. By requiring these rights to journal peer-reviewed and approved content, this draft policy not only infringes on the authors' right to retain and control the rights they want to confer, but also infringes on the rights of the publisher of the journal.

As a collective group of clinical medical publishing societies and consistent with our non-profit missions, we stand ready to continue to support a "green open access" approach to making the NIH policy work—preferably with an embargo. However, we cannot support a green model if the NIH insists on outsourcing the quality control of manuscripts produced by NIH grantees to our journals, usurping rights to reproduce and create derivative works from the content and infringing on our ability to recoup our expenses through subscriptions or other access models.

Further, as scientific societies that represent NIH funded researchers, we cannot support a policy that restricts the abilities of our members to choose where, how, and under what licenses they publish their research.

Draft Guidance on Publication Costs

We continue to be concerned that this policy draft will force more and more journals to flip to an Article Processing Charge funded open access model. If journals cannot recoup expenses through subscriptions because of zero embargo and have added concerns about the rights the NIH are requiring, moving to an APC model may provide a more sustainable revenue stream.

While the NIH has always contended that they are "business model agnostic," this draft policy fails to take into consideration the obvious market forces that will affect the industry. Because this draft policy extends the deposit requirements beyond the grant closing date and yet does not allow for researchers to use NIH grant money to pay publication fees for those papers, the draft policy adds a burden to the researchers. Hastening a move to more APC funded open access will be extremely expensive for US Institutions and authors as well as exacerbate the inequalities inherent in the APC model of open access globally as

well as with under-resourced domestic institutions, many of which support diverse students and investigators.

Deposit of Accepted Papers is Not Free

An argument could be made that a policy that requires authors to deposit a preprint (manuscripts prior to peer review) into PubMed Central is free. However, that is not this policy. This draft policy requires that manuscript deposits undergo extensive quality checks and rounds of improvements prior to deposit. These activities, as explained elsewhere, are not free.

Publisher agreements with the NLM require that publishers deposit "electronically readable versions of full-text journal articles and other journal content, at no expense to NLM" and "in XML format, using a mutually agreed upon DTD." Producing these formats and developing workflows for a subset of manuscripts to be delivered to the NLM, with associated metadata, incurs expense and staff resources.

Devaluing subscriptions by imposing zero-embargo on the quality approved and journal branded content comes at expense—in the form of loss of revenue-- for the journals and non-profit societies. To date, the NIH has not provided an Economic Impact Statement on the financial impact of this draft policy on American societies and publishers. This policy as drafted will disproportionately affect smaller societies, particularly those whose journals are not sustainable as fully APC funded open access journals.

The undersigned organizations make these comments collaboratively:

American Society of Clinical Oncology
American College of Physicians
NEJM Group
American Society of Anesthesiologists
American Thoracic Society
American Gastroenterological Association
Endocrine Society
American Academy of Neurology
American Psychiatric Association
American Epilepsy Society
American College of Chest Physicians
American Society of Nephrology